K051645

OCT 1 3 2005

510(k) SUMMARY
EVIS EXERA 160A SYSTEM

1. General Information

■ **Applicant**

Olympus Medical Systems Corp.
2951 Ishikawa-cho, Hachioji-shi,
Tokyo, 192-8507, Japan
Establishment Registration No.: 8010047

■ **Official Correspondent**

Laura Storms-Tyler
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Regulatory Affairs & Quality Assurance
Olympus America Inc.
Two Corporate Center Drive,
Melville, NY 11747-9058, USA
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Email: Laura.storms-tyler @olympus.com
Establishment Registration No.: 2429304

■ **Manufacturer**

Light source/Video system center: Shirakawa Olympus Co., Ltd.
3-1, Aza-Ookamiyama, Ooaza-Odakura, Nishigo-mura,
Nishishirakawa-gun, Fukushima, Japan 961-8061
Establishment Registration No.: 3002808148

Gastrointestinal scope/
Colonoscope: Aizu Olympus Co., Ltd.
500 Aza-Muranishi, Ooaza-lidera, Monden-cho,
Aizuwakamatsu-shi, Fukushima, Japan 965-8520
Establishment Registration No.: 9610595

2. Device Identification

■ Device Name: EVIS EXERA 160A System

■ Common Name: Endoscopic Video Imaging System

■ Class: II

■ Classification:

Table 16-1. Classification of the EVIS EXERA 160A System

Regulation Number	Regulation Name	Product Code	Classification Panel
876.1500	Endoscope and accessories	FDS- Gastroscope, Gastro-Urology FDF- Colonoscope, Gastro-Urology KOG- Endoscope and accessories GCT- Light Source, Endoscope, Xenon Arc	Gastroenterology & Urology

3. Legally Marketed Device to which Substantial Equivalence is Claimed

The following table shows the primary components (part of this submission) of the EVIS EXERA 160A System and each device to which we claim substantial equivalence (predicate device).

Table 16-2. Primary Components & Predicate Devices of the EVIS EXERA 160A System

Subject Device (Part of this Submission)	Predicate Device	PD's 510(k) No.
EVIS EXERA Xenon Light Source Olympus CLV-160A	EVIS Universal Light Source CLV-U40	K954451
EVIS EXERA Video System Center Olympus CV-160A	EVIS Video System Center CV-140	K954451
EVIS EXERA Gastrointestinal Videoscope XGIF-N160Y2	XGIF-N200H Gastrointestinal Videoscope	K001766
EVIS EXERA Gastrointestinal Videoscope XGIF-Q160Y5	EVIS EXERA Gastrointestinal Videoscope GIF-Q160Z	K011151
EVIS EXERA Gastrointestinal Videoscope XGIF-H160Y2		
EVIS EXERA Colonovideoscope XCF-Q160W6L	EVIS EXERA Colonoscope CF-Q160AL	K001241
EVIS EXERA Colonovideoscope XCF-H160AY2L		
EVIS EXERA Colonovideoscope XPCF-Q160AY2L	EVIS EXERA Colonovideoscope PCF-160AL	

4. Device Description

The EVIS EXERA 160A System consists of Olympus camera heads, endoscopes, video system center, light source, monitors, endo-therapy accessories and other ancillary equipment. This system is intended for endoscopic diagnosis, treatment and video observation of the upper and lower digestive tract.

The primary components of the subject system, which are part of this submission, are:

- EVIS EXERA Xenon Light Source Olympus CLV-160A,
- EVIS EXERA Video System Center Olympus CV-160A,
- EVIS EXERA Gastrointestinal Videoscopes XGIF-N160Y2, XGIF-Q160Y5, XGIF-H160Y2,
- EVIS EXERA Colonovideoscopes XCF-Q160W6L, XCF-H160AY2L, XPCF-Q160AY2L

The EVIS EXERA Xenon Light Source Olympus CLV-160A is intended for endoscopic diagnosis, treatment and video observation. The CLV-160A is basically identical to the predicate device, EVIS Universal Light Source CLV-U40, with the exception that the CLV-160A has an optional filter which allows the user to enhance endoscopic white light images by selective processing of green and blue light. This feature, referred to as Narrow Band Imaging (NBI) employs an optical filter to filter the white light spectrum, changing it from a broad band to a narrow band. Both an endoscopic image by standard white light illumination and that by NBI illumination can be obtained. The user can select either the standard observation mode by pressing the scope switch on the scope or the NBI mode switch on the CLV-160A. In comparison to conventional white light observation, NBI observation provides greater visual contrast of the surface structure and fine capillary patterns of the mucous membranes.

The EVIS EXERA Video System Center Olympus CV-160A is a video processing system intended for use with Olympus endoscopes such as the subject endoscopes. The CV-160A Video System Center contains the video signal processing technology which enables the endoscope to illuminate, enhance, view, record and transmit video data of endoscopic images. The CV-160A Video System Center is equivalent to predicate Olympusdevices which have the same basic functionality. Predicate Olympus devices include the EVIS Video System Center CV-140. The Video System Center CV-140 enabled the physician to utilize a variety of Olympus flexible endoscopes, including colonoscopes, gastroscopes, sigmoidscopes, duodenoscopes and bronchoscopes. The EVIS Video System Center CV-140 contains the video signal processor technology which allowed the various endoscopes to illuminate, enhance, view, record, and transmit video data of endoscopic images.

Compared to these predicate devices, the subject CV-160A incorporates the following changes:

1. The CV-160A is compatible with any specified Olympus flexible, both video and fiberoptic, and rigid endoscope.
2. The CV-160A processes the NBI image, generated by the CLV-160A light source and captured by the endoscope's Charged Coupled Device (CCD), creating an enhanced image of the tissue's vasculature.

Both the CLV-160A and CV-160A can be used with any specified Olympus flexible and rigid endoscope models, including gastroscopes, ultrasound gastroscopes, duodenoscopes, colonoscopes, sigmoidscopes, choledochoscopes, bronchoscopes, rhino-laryngoscopes, tracheal intubation scopes, transnasal esophago scopes, hysteroscopes, cystoscopes, ureterorenoscopes, laparo-thoracoscopes for conventional white light endoscopy. The flexible endoscopes which are the subject of this premarket notification are gastroscope and colonoscope models listed in Table 16-2.

Additionally, when they are combined with the new Gastrointestinal Videoscopes (XGIF-N160Y2, XGIF-Q160Y5, XGIF-H160Y2), and Colonovideoscopes (XCF-Q160W6L, XCF-H160AY2L, XPCF-Q160AY2L), both an endoscopic image by white light illumination and that by NBI illumination can be obtained. The user can select either the NBI mode or normal mode by pressing the scope switch on the scope or the NBI mode switch on the CLV-160A; the NBI filter in the CLV-160A is inserted on the light axis when the NBI mode is selected.

The new endoscopes are basically identical to each predicate device shown in Table 16-2 in intended use, and similar in specifications, performance and materials. The CV-160A identifies an NBI-compatible scope when it is connected by using the Scope ID function provided with the scopes.

5. Indications for Use

The EVIS EXERA 160A system consists of Olympus camera heads, endoscopes, video system center, light source, monitors, endo-therapy accessories and other ancillary equipment. This system is intended for endoscopic diagnosis, treatment and video observation of the upper and lower digestive tract. The indications for use of each primary component are shown below.

EVIS EXERA Xenon Light Source Olympus CLV-160A

This light source has been designed to be used with Olympus endoscopes, video system center, and other ancillary equipment for endoscopic diagnosis, treatment and video observation.

EVIS EXERA Video System Center Olympus CV-160A

This video system center has been designed to be used with Olympus camera heads, endoscopes, light source, monitors, endo-therapy accessories and other ancillary equipment for endoscopic diagnosis, treatment and video observation.

EVIS EXERA Gastrointestinal Videoscope XGIF-N160Y2

This instrument has been designed to be used with an Olympus video system center, light source, documentation equipment, video monitor, endo-therapy accessories (such as a biopsy forceps) and other ancillary equipment for transoral or transnasal observation and surgery within the upper digestive tract (including the esophagus, stomach and duodenum).

EVIS EXERA Gastrointestinal Videoscope XGIF-Q160Y5, XGIF-H160Y2

These instruments have been designed to be used with an Olympus video system center, light source, documentation equipment, video monitor, endo-therapy accessories (such as a biopsy forceps) and other ancillary equipment for endoscopy and endoscopic surgery within the upper digestive tract (including the esophagus, stomach and duodenum).

EVIS EXERA Colonovideoscope XCF-Q160W6L, XCF-H160AY2L, XPCF-Q160AY2L

These instruments have been designed to be used with an Olympus video system center, light source, documentation equipment, video monitor, endo-therapy accessories (such as a biopsy forceps) and other ancillary equipment for endoscopy and endoscopic surgery within the lower digestive tract (including the anus, rectum, sigmoid colon, colon and ileocecal valve).

6. Comparison of Technological Characteristics

Each primary component of the EVIS EXERA160A System is basically identical to its predicate device in intended use, and similar in specifications except for the addition of the NBI function. Comparison between the subject and predicate devices is shown in Table 16-3 to 16-10. The clinical literatures provided in this submission supports the safety and efficacy of NBI imaging in endoscopy.

Table 16-3. Comparison of Specifications
Subject Device: EVIS EXERA Xenon Light Source Olympus CLV-160A
Predicate Device: EVIS Universal Light Source CLV-U40 (K954451)

Specifications	Subject Device: CLV-160A	Predicate Device: CLV-U40
Power Supply	100-240V~ ±10%, 50/60Hz ± 1Hz	120V~ ±10%, 50/60Hz ± 1Hz
Over-current Protection	Fuse type	Circuit breaker type
Input Current	500VA (at observation)	6A (at observation) 8A (at flash)
Size	381(W) × 162(H) × 536(D)mm	587(W) × 165(H) × 537(D)mm
Weight	15.4kg	20kg
Compatible Endoscopes	Videoscope Fiberscope Rigid scope	Videoscope Fiberscope Rigid scope

Examination Lamp	Xenon short-arc lamp (ozone-free)300W	Xenon short-arc lamp (ozone-free)300W
Average Lamp Life	Approximately 500 hours of continuous use	Approximately 500 hours of continuous use
Emergency Lamp	Halogen lamp 12V 35W	Halogen lamp(without mirror) 24V 150W
Average Emergency Lamp Life	Approximately 500 hours	Approximately 500 hours
NBI Filter	NBI filter	NA
Brightness Control	Automatic and Manual	Automatic and Manual
Automatic Exposure	17 steps	17 steps + F
Photography Function	-	Provided
Air Feeding	4 levels available (off, low, mid, high)	4 levels available (off, low, mid, high)
Air Feeding Pump	Diaphragm type pump	Linear type pump
System Connector	Provided	Provided
Foot Switch Connector	Provided	Provided
CV Connector	Provided	Provided
Cooling Air Direction	Rear	Left side
Type of Protection against Electric Shock	Class?	Class?
Degree of Protection against Electric Shock of Applied Part	TYPE BF or CF applied part (Depend on applied part)	TYPE BF applied part
Applicable Standard	UL60601-1	UL544

Table 16-4. Comparison of Specifications
Subject Device: EVIS EXERA Video System Center Olympus CV-160A
Predicate Device: EVIS Video System Center CV-140 (K954451)

Specification		Subject Device: CV-160A	Predicate Device: CV-140
Power Supply		100-240V~ ±10%? 50/60Hz ± 1Hz	120V~ ±10%? 50/60Hz ± 1Hz
Over-current Protection		Fuse type	Circuit breaker type
Input Current		150VA	0.8A
Size		370(W) × 91(H) × 462 (D)mm	450(W) × 72(H) × 465(D)mm
Weight		10.6 kg	10 kg
Compatible Endoscopes		· Fiber/rigid scope via camera head · Videoscope	· Gastro/colono/sigmoid/duodeno/ broncho videoscope · Fiberscope via video converter
Observation	Video Signal Output	RGB:3 Y/C:4 VBS:4 HDTV:1	RGB:3 Y/C:3 VBS:4
	Auto White balance	Automatically adjusted using the white balance switch. At the time of connection with the scope in which Scope ID is provided, compensation is performed automatically.	Automatically adjusted using the white balance switch
	Standard Color Chart Output	Color bar image	Color bar image 50% white
	Color Tone Adjustment	R: ±8 steps B: ±8 steps CHROMA: ±8steps	R control: ±7 steps B control: ±7steps HSR control: ±7steps
	Automatic Gain Control (AGC)	Provided	Provided
	Image Enhancement	Edge enhancement: [OFF] [Low] [Med] [High] 4 levels available Structure enhancement:[OFF] [Low] [Med] [High] 4 levels available	Image enhancement: [Low] [Med] [High] 3 levels available
	Iris Mode Selection	AUTO/ PEAK EXPOSURE Electrical shutter	AVE/ PEAK
	Optical Zoom	× 1/ × 1.2 / × 1.5: 3-Mode	-
	NBI Observation	NBI function	-
	Picture in Picture	The image of an external device connected to this instrument is displayed on the main monitor together with the endoscopic image.	The frozen endoscopic image is displayed on the sub screen when the freeze mode is selected.
Communication with Scope		Provided	-
Foot Switch Connector		Provided	-
Record to Memory Card		Provided	-
Type of Protection against Electric Shock		Class?	Class?
Degree of Protection against Electric Shock of Applied Part		TYPE BF or CF applied part (Depend on applied part)	TYPE BF applied part
Applicable Standard		UL60601-1	UL544

Table 16-5. Comparison of Specifications
Subject Device: EVIS EXERA Gastrointestinal Videoscope XGIF-N160Y2
Predicate Device: XGIF-N200H Gastrointestinal Videoscope (K001766)

Specifications	Subject Device XGIF-N160Y2	Predicate Device XGIF-N200H
Field of View	120 °	120 °
Depth of Field	3-100mm	3-100mm
Direction of Forward View	0 °	0 °
Type of CCD	Color	Monochrome
Outer Diameter of Distal End	4.9mm	6mm
Outer Diameter of Insertion Tube	4.9mm	6mm
Bending Section Angulation	UP: 210 ° DOWN:120 °	UP: 180 ° DOWN: 180 ° RIGHT: 160 ° LEFT: 160 °
Working Length	1100mm	925mm
Inner Diameter of Instrument Channel	2.0mm	2.0mm

Table 16-6. Comparison of Specifications
Subject Device: EVIS EXERA Gastrointestinal Videoscope XGIF-Q160Y5
Predicate Device: EVIS EXERA Gastrointestinal Videoscope GIF-Q160Z (K011151)

Specifications	Subject Device XGIF-Q160Y5	Predicate Device GIF-Q160Z
Field of View	140 °	140 ° (in WIDE position) 75 ° (in TELE position)
Depth of Field	3-100mm	8-100mm (in WIDE position) 1.5-3mm (in TELE position)
Direction of Forward View	0 °	0 °
Type of CCD	Color	Color
Outer Diameter of Distal End	8.8mm	10.8mm
Outer Diameter of Insertion Tube	8.8mm	10.9mm
Bending Section Angulation	UP:210 ° DOWN:90 ° RIGHT:100 ° LEFT:100 °	UP: 210 ° DOWN: 90 ° RIGHT:100 ° LEFT:100 °
Working Length	1030mm	1030mm
Inner Diameter of Instrument Channel	2.8mm	2.8mm
Zoom Magnification Function	No	Yes

Table 16-7. Comparison of Specifications
Subject Device: EVIS EXERA Gastrointestinal Videoscope XGIF-H160Y2
Predicate Device: EVIS EXERA Gastrointestinal Videoscope GIF-Q160Z (K011151)

Specifications	Subject Device XGIF-H160Y2	Predicate Device GIF-Q160Z
Field of View	140 °	140 ° (in WIDE position) 75 ° (in TELE position)
Depth of Field	2-100mm	8-100mm (in WIDE position) 1.5-3mm (in TELE position)
Direction of Forward View	0 °	0 °
Type of CCD	Color	Color
Outer Diameter of Distal End	9.8mm	10.8mm
Outer Diameter of Insertion Tube	9.8mm	10.9mm
Bending Section Angulation	UP: 210 ° DOWN: 90 ° RIGHT:100 ° LEFT:100 °	UP: 210 ° DOWN: 90 ° RIGHT:100 ° LEFT:100 °
Working Length	1030mm	1030mm
Inner Diameter of Instrument Channel	2.8mm	2.8mm
Zoom Magnification Function	No	Yes

Table 16-8. Comparison of Specifications
Subject Device: EVIS EXERA Colonovideoscope XCF-Q160W6L
Predicate Device: EVIS EXERA Colonovideoscope CF-Q160AL (K001241)

Specifications	Subject Device XCF-Q160W6L	Predicate Device CF-Q160AL
Field of View	170 °	140 °
Depth of Field	3-100mm	3 -100mm
Direction of Forward View	0 °	0 °
Type of CCD	Color	Color
Outer Diameter of Distal End	13.2mm	12.8mm
Outer Diameter of Insertion Tube	12.8mm	12.8mm
Bending Section Angulation	UP: 180 ° DOWN: 180 ° RIGHT:160 ° LEFT:160 °	UP: 180 ° DOWN: 180 ° RIGHT:160 ° LEFT:160 °
Working Length	1680mm	1680mm
Inner Diameter of Instrument Channel	3.7mm	3.7mm
Flexibility of Insertion Tube	Adjustable by the user.	Adjustable by the user.

Table 16-9. Comparison of Specifications
Subject Device: EVIS EXERA Colonovideoscope XCF-H160AY2L
Predicate Device: EVIS EXERA Colonovideoscope CF-Q160AL (K001241)

Specifications	Subject Device XCF-H160AY2L	Predicate Device CF-Q160AL
Field of View	170 °	140 °
Depth of Field	2 -100mm	3 -100mm
Direction of Forward View	0 °	0 °
Type of CCD	Color	Color
Outer Diameter of Distal End	13.9mm	12.8mm
Outer Diameter of Insertion Tube	12.8mm	12.8mm
Bending Section Angulation	UP: 180 ° DOWN:180 ° RIGHT:160 ° LEFT:160 °	UP: 180 ° DOWN:180 ° RIGHT:160 ° LEFT:160 °
Working Length	1680mm	1680mm
Inner Diameter of Instrument Channel	3.7mm	3.7mm
Flexibility of Insertion Tube	Adjustable by the user.	Adjustable by the user.

Table 16-10. Comparison of Specifications
Subject Device: EVIS EXERA Colonovideoscope XPCF-Q160AY2L
Predicate Device: EVIS EXERA Colonovideoscope PCF-160AL (K001241)

Specifications	Subject Device XPCF-Q160Y2L	Predicate Device PCF- 160AL
Field of View	140 °	140 °
Depth of Field	3-100mm	3 -100mm
Direction of Forward View	0 °	0 °
Type of CCD	Color	Color
Outer Diameter of Distal End	11.3mm	11.3mm
Outer Diameter of Insertion Tube	11.5mm	11.5mm
Bending Section Angulation	UP: 180 ° DOWN: 180 ° RIGHT:160 ° LEFT:160 °	UP: 180 ° DOWN: 180 ° RIGHT:160 ° LEFT:160 °
Working Length	1680mm	1680mm
Inner Diameter of Instrument Channel	3.2mm	3.2mm
Flexibility of Insertion Tube	Adjustable by the user.	Adjustable by the user.

6. Conclusion

When compared to the predicate devices, the EVIS EXERA 160A System does not incorporate any significant changes in intended use, method of operation, material, or design that could affect the safety or effectiveness of the system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 13 2005

Ms. Laura Storms-Tyler
Executive Director, Regulatory Affairs
and Quality Assurance
Olympus America, Inc.
Two Corporate Center Drive
MELVILLE NY 11747-3157

Re: K051645
Trade/Device Name: EVIS EXERA 160A System
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Codes: NWB, FDS and FDF
Dated: September 2, 2005
Received: September 6, 2005

Dear Ms. Storms-Tyler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K051645

Device Name: EVIS EXERA 160A System

Indications For Use:

EVIS EXERA Xenon Light Source Olympus CLV-160A

This light source has been designed to be used with Olympus endoscopes, video system center, and other ancillary equipment for endoscopic diagnosis, treatment and video observation.

EVIS EXERA Video System Center Olympus CV-160A

This video system center has been designed to be used with Olympus camera heads, endoscopes, light source, monitors, endo-therapy accessories and other ancillary equipment for endoscopic diagnosis, treatment and video observation.

EVIS EXERA Gastrointestinal Videoscope XGIF-N160Y2

This instrument has been designed to be used with an Olympus video system center, light source, documentation equipment, video monitor, endo-therapy accessories (such as a biopsy forceps) and other ancillary equipment for transoral or transnasal observation and surgery within the upper digestive tract (including the esophagus, stomach and duodenum).

Prescription Use ✓ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K051645

Indications for Use

510(k) Number (if known): K051645

Device Name: EVIS EXERA 160A System

Indications For Use:

EVIS EXERA Gastrointestinal Videoscope XGIF-Q160Y4, XGIF-Q160Y5, XGIF-H160Y1, XGIF-H160Y2

These instruments have been designed to be used with an Olympus video system center, light source, documentation equipment, video monitor, endo-therapy accessories (such as a biopsy forceps) and other ancillary equipment for endoscopy and endoscopic surgery within the upper digestive tract (including the esophagus, stomach and duodenum).

EVIS EXERA Colonovideoscope XCF-Q160W3L, XCF-Q160W6L, XCF-H160AYL, XCF-H160AY2L, XPCF-Q160AYL, XPCF-Q160AY2L

These instruments have been designed to be used with an Olympus video system center, light source, documentation equipment, video monitor, endo-therapy accessories (such as a biopsy forceps) and other ancillary equipment for endoscopy and endoscopic surgery within the lower digestive tract (including the anus, rectum, sigmoid colon, colon and ileocecal valve).

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David R. Segerson

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K051645